DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

January 14, 2000

WARNING LETTER
CHI-11-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Brian A. Tambi, President/CEO
Morton Grove Pharmaceuticals, Inc.
6451 W. Main Street
Morton Grove, IL 60053

Dear Mr. Tambi:

During an inspection of your drug manufacturing facility located at the above address, conducted from November 16, 1999 through December 16, 1999, FDA investigators Yvonne Lozano and Nicholas Lyons found serious deviations from the current Good Manufacturing Practice Regulations (cGMP)(Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

- Failure to conduct sufficiently thorough and adequately detailed investigations as required by 21 CFR 211.192. For example:

  a. The stability failure investigations for Clindamycin Phosphate Topical Solution, lots 21796 and 22334, were not complete in that there was no documented action plan, conclusion, or corrective action, and the investigation did not extend to other batches which may be associated with the identified degradant problem.

  b. The stability failure investigation for Tretinoin Topical Solution, lot 22494, was not complete in that there was no documented action plan, conclusion, or corrective action, and the investigation did not extend to other batches which may be associated with the identified degradant problem.

  c. The stability failure investigation for Myphetane DC-CS, lot 21674, was not complete in that there was no documented action plan, conclusion, or corrective action, and the investigation did not extend to other batches which may be associated with the identified codeine potency problem.

- Failure to conduct sufficient cleaning validation as required by 21 CFR 211.100. The previous inspection conducted from March 3, 1999 to April 12, 1999, documented cross-contamination of drug products which was attributed to insufficient cleaning procedures. In your May 5, 1999 response to the FDA-483

dated April 12, 1999, you stated "....validation studies...will be undertaken to revalidate the established method. The timeline...is end of June, 1999..." You wrote a follow-up response dated July 23, 1999, in which you stated, "...we expect to complete implementation by December, 1999." The current inspection revealed that cleaning validations for 19 of 20 products have not been completed nor scheduled.

- Failure to establish sufficient production and process control procedures as required by 21 CFR 211.100(a) and failure to follow established procedures as required by 21 CFR 211.100(b). The effects of in-process changes on the established/validated process are not considered prior to implementing the changes. For example:

  a. Silicon tubing was used instead of the stainless steel tubing (as authorized in the established process) in filling lot 22454. The batch was later rejected due to an extraneous peak in the HPLC analysis.

  b. Batch 22687, Triamcinolone Acetonide Lotion 1%, was mixed at two different speeds, more than a week apart. The mixing instructions were authorized by use of two separate in-process change records, one of which failed to include authorization signatures. The batch was not filled in one day as required by the established process.

- Failure to establish procedures to assure the absence of objectionable microorganisms as required by 21 CFR 211.113(a). The established procedures for investigating microbiological out of specification results do not require identification of microbial isolates. A laboratory procedure for the identification of microbial isolates has not been established as required by 21 CFR 211.160.

The above list of violations is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that all of your firm's products are in compliance with all requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunctions.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the

delay and the time within which corrections will be completed. Your response should be addressed to: Richard Harrison, Compliance Director, at the address provided in the letterhead.

Sincerely,

\s\
Raymond V. Mlecko
District Director